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- B** Data Collection
- C** Statistical Analysis
- D** Data Interpretation
- E** Manuscript Preparation
- F** Literature Search
- G** Funds Collection

Is the pull-out force of the Meniscus Arrow in bone affected by the inward curling of the barbs during biodegradation? An *in vitro* study

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| Background: | Summary |
| | Inward curling of the barbs of Meniscus Arrows during degradation was observed in a previous study, in which swelling, distention, and water uptake by Meniscus Arrows was evaluated. This change of configuration could have consequences with respect to anchorage capacity in bone. |
| | Material/Methods: Eight non-degraded Meniscus Arrows in the original configuration were pulled out of thawed, fresh-frozen human femoral condyle, and pull-out force was measured and compared with that of 6 Meniscus Arrows after 31 days of degradation under controlled conditions. |
| | Results: No significant difference was found between the 2 groups with respect to the required pull-out force (<i>t</i> test), the distribution of the data, or the interaction between degradation and location, as evaluated by Mann-Whitney test, and no significant difference was found between the 2 groups with respect to the degradation state or position in the condyles, as evaluated by 2-way analysis of variance. |
| | Conclusions: Our results indicate that the decrease in barb-barb diameter during the first month of degradation of the Meniscus Arrows has no significant effect on the tensile pull-out force required for removal from human femur condyle. Further research should be undertaken to examine whether the same is true for other biodegradable devices with barbs. |
| key words: | biodegradable implants • pull-out force • <i>in vitro</i> • Meniscus Arrow • surgical fixation devices |

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BACKGROUND

Metallic fixation devices such as screws [1,2], pins [3–5], and staples [6] are generally used to fix small bony fragments in fracture treatment. Most require a second procedure for removal. When inserted into joints, removal is, in most circumstances, obligatory to prevent damage of the opposing cartilage. Even when embedded under the cartilage surface, protrusion can occur [7,8]. Removal prevents scattering during computed tomography or magnetic resonance imaging and also prevents localized tissue reactions [9–11].

The use of biodegradable devices obviates the need for removal, and researchers have spent the last 3 decades in the development of appropriate materials and devices. At present, different biodegradable polymers, such as polydioxanone, polyglycolic acid, and polylactic acid and their copolymers, combinations, and blends, are available. Biodegradable screws or pins are applied for small-fragment fixation in fracture treatment or treatment of osteochondritis dissecans. Screws and pins have specific advantages and disadvantages. Biodegradable screws produce the required compression, but their current minimum head diameter of 3 mm is considerable for the often fragile fragments. In addition, at least 2 devices are necessary to achieve rotational stability. Furthermore, during the degradation process, wear of the opposing cartilage and local tissue reactions can occur [12,13]. Biodegradable pins do not share these disadvantages but do not provide compression [14,15].

The Meniscus Arrow (MA; ConMed Linvatec Ltd., Tampere, Finland) is a biodegradable, nail-like device composed of L/DL (80/20) self-reinforced lactide copolymer with a very small core diameter (1.1 mm), barbs, and a small, flat head (Figure 1). Originally designed to mend ruptured menisci, the anchorage of MAs in bone was examined in a previous *in vitro* study to evaluate the potential application in fixing small cartilage-bone fragments in the treatment of osteochondritis dissecans and in small-fragment fracture surgery [16]. Theoretically, biodegradable polymers swell during degradation, which could prove an additional advantage for the use of biodegradable implants in fracture fixation. Their hold in bone would increase like an expanding bolt. For gels, this distention is variable [17–21], and we found that the swelling of MAs is negligible with respect to this mechanical aspect [22]. In the same study, we observed consistent inward curling of the barbs of all MAs during the degradation process (Figure 2) [22]. This phenomenon could result in a decreased hold in bone. Therefore, the aim of the present study was to evaluate the potential influence of this inward curling of the barbs on the required pull-out force from bone.

MATERIAL AND METHODS

Group 1 (non-degraded MAs) consisted of 8 MAs retrieved directly from the packaging. In group 2 (degraded MAs), 6 MAs were submerged over a period of 31 days in sterile phosphate-buffered saline (Pharmacy of the University Medical Centre, Groningen, the Netherlands) at 37°C. The solution was changed twice a week under sterile conditions. A degradation period of 31 days was selected because this period is the expected initial consolidation time for small-fragment fractures in humans.



Figure 1. Photograph of a Meniscus Arrow.

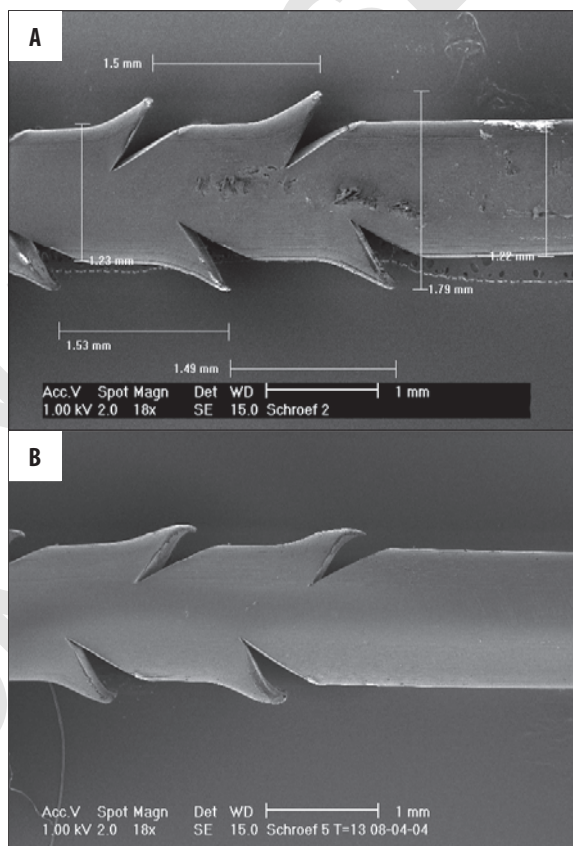


Figure 2. (A) A non-degraded Meniscus Arrow. (B) A Meniscus Arrow after 31 days of immersion in sterile saline solution.

For the experiment, 18 holes of 1.0 mm in diameter were drilled into both condyles of a thawed, previously fresh-frozen human cadaver femur, to exclude the influence of potential differences of local bone density (Figure 3). Alternating non-degraded and degraded MAs were then inserted via a hole in an extracting device and gently hammered into each drill hole (Figure 4). Standard hand-insertion instruments were used. The MAs were subsequently pulled out with an Instron 1195 draw-bench (Instron, 825 University Ave. Norwood, MA 02062-2643, USA). The load cell measured 1000 newtons (N) maximum, with a scale set at 0N to 200N. The extraction speed applied to the device was 5 mm/minute.

Statistical analysis

Results were analyzed statistically by *t* test, Mann-Whitney test, and 2-way analysis of variance.

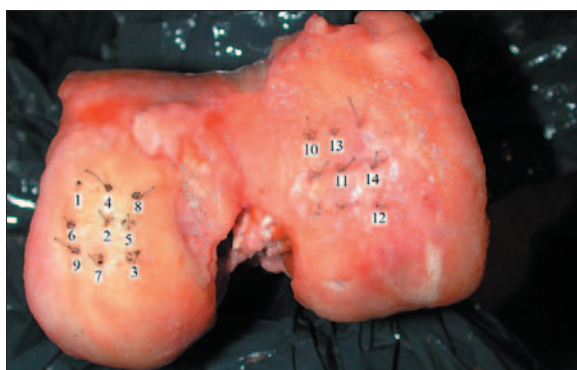


Figure 3. The series of drill holes in the femur condyle.

Table 1. Peak pull-out force of meniscus arrows from condyle.

| Non-degraded arrows | | Degraded arrows | |
|---------------------|--------------------|-----------------|--------------------|
| Arrow number | Pull-out force (N) | Arrow number | Pull-out force (N) |
| 1* | 41.19 | 2* | 22.75 |
| 3* | 14.42 | 4* | 21.29 |
| 5* | 12.82 | 6* | 12.80 |
| 7* | 21.05 | 9** | 34.22 |
| 8* | 34.99 | 10** | 24.85 |
| 11** | 38.06 | 12** | 15.09 |
| 13** | 28.95 | | |
| 14** | 37.43 | | |
| Average (SD) | 28.61 (11.17) | | 21.83 (7.63) |

* Lateral condyle; ** medial condyle. SD – standard deviation.

RESULTS

In group 1, the peak required pull-out force of the 8 non-degraded MAs ranged from 12.82N to 41.19N, with an average \pm standard deviation of 28.61 ± 11.17 N (Table 1). In group 2, the required pull-out force for degraded MAs ranged from 12.80N to 34.22N, with an average of 21.83 ± 7.63 N.

The average extraction force of the new, non-degraded MAs and the degraded MAs did not differ significantly (*t* test, $P=.23$, 95% confidence interval for the difference in means: $[-4.8; 18.4]$). In addition, the spread of the results did not differ significantly (Levene's test, $P=0.16$). Results of 2-way analysis of variance showed no significant difference between degradation and location ($P=.7$), between degraded and non-degraded MAs ($P=.15$), or between location in the lateral or medial condyle ($P=.14$).

DISCUSSION

The use of biodegradable devices is advantageous if the fixation lasts long enough to allow for consolidation with minimal damage to the fixed bony fragments and if the degradation occurs without adverse effects. The Meniscus Arrow is one such potential fixation device [14,15,22], but the inward curling of the barbs, encountered in our previ-

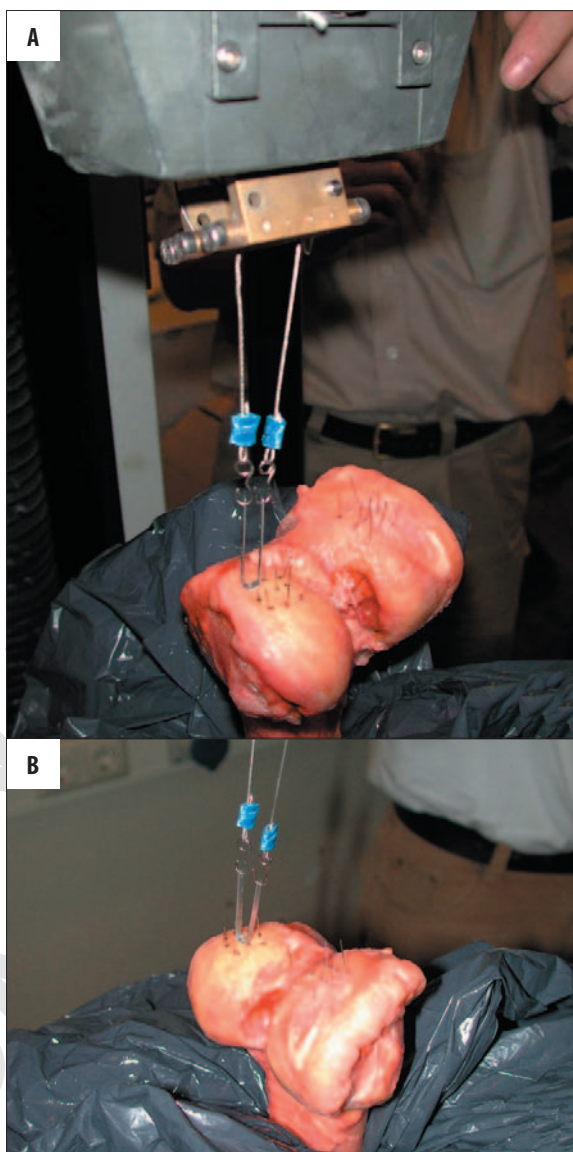


Figure 4. (A) Initiation of extraction of the first Meniscus Arrow from hole 1. (B) Initiation of extraction of the second Meniscus Arrow from hole 2.

ous study (22), could lead to decreased anchorage in the bone over time. We found no other reports describing this curling or its potential effect on the hold of MAs or other biodegradable devices. This provided the impetus for the present study.

Although the inward curling of the barbs after a degradation period of 31 days suggests that this could lead to a decrease in the anchorage to a solid material such as bone, this is not confirmed in the present study. Therefore, this phenomenon does not appear to interfere with the application of MAs in fixing small bony fragments in fracture surgery or in osteochondritis dissecans.

CONCLUSIONS

The inward curling of the barbs of MAs during degradation did not affect the anchorage in bone in our tests. Whether

other biodegradable devices with barb-like restraints deform spontaneously during degradation will require additional research.

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